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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/596,429 | 06/15/2000 | Raymond Paul Goodrich JR. | 27-98B | 1651 |

23713 7590 06/03/2004

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| EXAMINER | |
|---|---|
| CHORBAJI, MONZER R | |
| **ART UNIT** | **PAPER NUMBER** |
| 1744 | |

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/596,429 | GOODRICH ET AL. | |
| | Examiner | Art Unit | |
| | MONZER R CHORBAJI | 1744 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 June 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ■ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

**1.** The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

**2.** Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 51, line 1; applicant uses the phrase "said fluid contains between about 0 to about 25%". However, the applicant does not provide what species the fluid contains that falls within this range. Explanation and rewarding of the claim is needed to understand the meaning of claim 51.

**3.** Claims 2-4 recite the limitation "said adding step" in line 1. There is insufficient antecedent basis for this limitation in the claim.

### *Claim Rejections - 35 USC § 102*

**4.** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**5.** Claims 1-2, 4-13, 15-23, 26-27, 31-38, 40-50, 53-58, 75-103, and 106-108 are rejected under 35 U.S.C. 102(b) as being anticipated by Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 1, 50, 78, 84, 97-98, and 106-107, Goodrich, Jr. et al discloses a method and an apparatus for inactivating microorganisms in fluids (col.3, lines 59-65) including the following: adjusting (i.e., removing) the percentage of plasma or bilirubin (col.24, line 51), mixing (col.24, lines 56-58), exposing the fluid to photoradiation (col.24, lines 64-65), a source of light (figure 7, 160), means for maintaining the fluid in the light path (figure 7, 164 and col.17, lines 39-41), a container (figure 7, 164, col.13, lines 6-8, and col.24, line 51), means for adjusting the plasma content of the fluid (col.24, lines 49-52), means for mixing (figure 7, 186), a photopermeable container (figure 7, 164 and col.13, lines 18-19), means for producing selected flow rate (figure 7, 184), and means for agitating the container (col.8, lines 34-36).

With respect to claims 2, 4-13, 15-23, 26-27, 31-38, 40-49, 53-58, 75-77, 79-103, and 108, Goodrich, Jr. et al teaches the following: mixing step occurs after adjusting step (col.24, lines 51-52 and lines 60-62), both steps occur simultaneously (col.23, lines 29-33), diluting solution to a desired concentration of plasma (col.24, lines 60-62), saline (col.13, line 13), buffer (col.13, line 13), nutrients (col.13, lines 16-19), phosphate (col.13, lines 27-28), cell storage solution (col.13, lines 16-19), an anticoagulant (col.12, lines 45-46), a cryoperservative solution (col.13, lines 25-29), washing the fluid (col.24, lines 60-62), photosensitizer is a photo-activatable compound (col.6, lines 4-10), photosensitizer is 7,8-dimethyl-10-ribityl isoalloxazine (col.5, line 55), bacterial (col.4, line 15), HIV viruses (col.4, line 17), photoradiation in the visible spectrum (col.8, lines 64-65), photoradiation in the ultraviolet spectrum (col.8, line 63),

photoradiation is in both the visible and ultraviolet spectra (col.8, lines 64-66), half the light in the visible spectrum and the other half in the ultraviolet spectrum (col.8, lines 66-67), plasma is adjusted to be within about 0 to about 50 percent of the total volume of the fluid (col.24, lines 60-62), photosensitizer is added to anticoagulant and the anticoagulant is added to the fluid (col.9, lines 65-67), enhancer is added to fluid prior to photoradiation of the fluid (col.10, lines 1-5), adenine (col.10, line 5), flowing the fluid containing photosensitizer past a source of photoradiation (col.9, lines 51-56), fluid and photosensitizer are contained in a photoradiation transparent container (col.10, lines 55-56), agitating during exposing (col.9, lines 57-61), placing fluid in a container transparent to photoradiation then adding photosensitizer to fluid and agitating the container (col.24, lines 60-62 and col.9, lines 57-61), adjusting the percentage of plasma before placing fluid in the container (col.24, lines 60-62 and lines col.25, lines 13-15), plasma is adjusted simultaneously with placing fluid in container (col.23, lines 29-35), adding nutrients (coll13, lines 16-19), nutrients and photosensitizer are present in the container prior to addition of fluid (col.18, lines 42-44), blood constituents (col.4, line 41), whole blood (col.4, line 39), separated blood product (col.4, lines 41-43), consists essentially of platelets (col.24, lines 51-52), consists essentially of serum (col.4, lines 42-43), consists essentially of plasma (col.4, line 32), consists essentially of red blood cells (col.4, lines 41-42), adding sufficient additives so that proteins remains biologically active after exposing (col.10, lines 2-4), photosensitizer is present at a concentration of between about 1 to about 200 micromolar (col.24, lines 61-63), photoradiation is between about 400 and

about 500 nm (col.8, line 62), photoradiation is between about 100 and about 500 j / cm^2 (col.8, line 61), photoradiation is between about 100 and about 200 nm (col.9, lines 49-50), therapeutic protein (col.4, lines 44-45), factor VIII (col.4, line 46), a support surface substantially parallel to the source of light (figure 7, 164), light emitting diodes (figure 7, 160), a reflective surface (figure 7, 163), a light guide (figure 7, 162), a temperature monitor (figure 7, 192), temperature controller such as a fan (col.17, lines 41-43), means for flowing the fluid (figure 7, 170, 184, 186, and 188), container is a transparent plastic bag (col.28, example 12), container is a transparent rigid plastic container (figure 7, 164), a shaker table (col.9, line 57), photopermeable container contains photosensitizer prior to addition of fluid (col.18, lines 42-44), and a lowered plasma content than occurs naturally (col.13, lines 18-19).

### *Claim Rejections - 35 USC § 103*

**6.** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

**7.** The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**8.** This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**9.** Claims 3, 14, 24-25, 28-30, 39, 51-52, 59-74, 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodrich, Jr. et al (U.S.P.N. 6,277,337).

With respect to claims 28-29, 51-52, 59, 60-61, and 68-69, Goodrich, Jr. et al adjusts the plasma content to about 30% of the total volume (col.24, lines 60-62) of plasma but fails to disclose adjusting the plasma content to other values. However, it would be obvious to one having ordinary skill in the art to modify the plasma content in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein even if such an adjustment is not taught in the reference.

With respect to claims 3, 39, and 104, Goodrich, Jr. et al adjust the plasma content either before adding the photosensitizer or while adding the

photosensitizer, but fails to disclose adjusting the plasma content after adding the photosensitizer. However, Goodrich, Jr. et al teaches diluting the plasma content (col.13, lines 18-19) such that it would be obvious to one having ordinary skill in the art to adjust the plasma either before or after the addition of the photosensitizer in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein even if such a concept is not taught in the reference.

With respect to claim 14, Goodrich, Jr. et al teaches washing or reducing the content of the plasma (col.13, lines 18-19). However, it would be obvious to one having ordinary skill in the art to wash the plasma as many times as required in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein.

With respect to claims 24-25, Goodrich, Jr. et al teaches that other ratios of visible and ultraviolet spectra can be used (col.9, lines 1-2) such that it would be obvious to use various ratios of visible and ultraviolet spectra in order for the radiation to completely inactivate microorganisms present therein.

With respect to claim 30, Goodrich, Jr. et al teaches adjusting the content of plasma in the fluid, but fails to disclose such a range. However, it would be obvious to one having ordinary skill in the art to adjust the content of plasma in order to prepare the fluid in a proper condition for the radiation to completely inactivate microorganisms present therein even if such a concept is not taught in the reference.

With respect to claims 62-67, 70-74, and 105, such claims are already discussed above with regard to claims 16, 55-58, and 102.

***Conclusion***

**10.** The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Goodrich, Jr. et al (U.S.P.N. 6,258,577), Platz et al (U.S.P.N. 6,268,120), McBurney et al (U.S.P.N. 6,548,241), Platz et al (U.S.P.N. 6,187,572), and Sowemimo-Coker et al (U.S.P.N. 6,235,508) teach similar concepts in inactivating fluids, which contains microorganisms.

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

**12.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

**13.** Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji
Patent Examiner
AU 1744
June 2, 2004

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